

CLAIMS:

1. A method for diagnosis of breast cancer in a subject, for determining the stage or severity of breast cancer in a subject, for identifying a subject at risk of developing breast cancer, or for monitoring the effect of therapy administered to a subject having breast cancer, said method comprising:

(a) analyzing a test sample of tissue from the subject by two dimensional electrophoresis to generate a two-dimensional array of features, said array comprising at least one chosen feature whose relative abundance correlates with the presence, absence, stage or severity of breast cancer or predicts the onset or course of breast cancer; and

(b) comparing the abundance of each chosen feature in the test sample with the abundance of that chosen feature in body fluid from one or more persons free from breast cancer, or with a previously determined reference range for that feature in subjects free from breast cancer, or with the abundance at least one Expression Reference Feature (ERF) in the test sample.

2. The method of claim 1, wherein the tissue is breast tissue.

3. The method of claim 1, wherein said method is for screening or diagnosis of breast cancer and the relative abundance of at least one chosen feature correlates with the presence or absence of breast cancer.

4. The method of claim 1, wherein said method is for monitoring the effect of therapy administered to a subject having breast cancer and the relative abundance of at least one chosen feature correlates with the severity of breast cancer.

5. The method of claim 2, wherein step (b) comprises comparing the abundance of each chosen feature in the sample with the abundance of that chosen feature in breast tissue from one or more persons free from breast cancer or with a previously determined reference range for that chosen feature in subjects free from breast cancer.

6. The method of claim 1, wherein step (b) comprises quantitatively detecting one or more Breast Cancer-Associated Features (BFs) selected from the group consisting of:

BF-1, BF-2, BF-3, BF-4, BF-5, BF-6, BF-7, BF-8, BF-9, BF-10, BF-11, BF-12, BF-13, BF-14, BF-15, BF-16, BF-17, BF-19, BF-20, BF-21, BF-22, BF-23, BF-24, BF-25, BF-26, BF-27, BF-31, BF-33, BF-34, BF-35, BF-36, BF-37, BF-38, BF-39, BF-40, BF-41, BF-42, BF-43, BF-44, BF-45, BF-46, BF-47, BF-48, BF-49, BF-50, BF-51, BF-52, BF-53, BF-54, BF-55, BF-56, BF-57, BF-60, BF-62, BF-64, BF-65, BF-67, BF-71, BF-72, BF-73, BF-75, BF-76, BF-78, BF-80, BF-81, BF-83, BF-84, BF-85, BF-86, BF-89, BF-90, BF-92, BF-94, BF-99, BF-101, BF-102, BF-103, BF-106, BF-112, BF-114, BF-122, BF-123, BF-125, BF-126, BF-127, BF-131, BF-134, BF-135, BF-137, BF-138, BF-201, BF-202, BF-203, BF-204, BF-205, BF-206, BF-207, BF-208, BF-209, BF-210, BF-211, BF-212, BF-213, BF-214, BF-215, BF-216, BF-217, BF-218, BF-219, BF-220, BF-221, BF-222, BF-223, BF-224, BF-225, BF-226, BF-227, BF-228, BF-229, BF-230, BF-231, BF-232, BF-233, BF-234, BF-235, BF-236, BF-237, BF-238, BF-239, BF-240, BF-241, BF-242, BF-243, BF-244, BF-245, BF-246, BF-247, BF-248, BF-249, BF-250, BF-251, BF-252, BF-253, BF-254, BF-255, BF-256, BF-257, BF-258, BF-259, BF-260, BF-261, BF-262, BF-263, BF-264, BF-265, BF-266, BF-267, BF-268, BF-269, BF-270, BF-271, BF-272, BF-273, BF-274, BF-275, BF-276, BF-277, BF-278, BF-279, BF-280, BF-281, BF-282, BF-283, BF-284, BF-285, BF-286, BF-287, BF-288, BF-289, BF-290, BF-291, BF-292, BF-293, BF-294, BF-295, BF-296, BF-297, BF-298, BF-299, BF-300, BF-301, BF-302, BF-303, BF-304, BF-305, BF-306, BF-307, BF-308, BF-309, BF-310, BF-311, BF-312, BF-313, BF-314, BF-315, BF-316, BF-317, BF-318, BF-319, BF-320, BF-321, BF-322, BF-323, BF-324, BF-325, BF-326, BF-327, BF-328, BF-329, BF-330, BF-331, BF-332, BF-333, BF-334, BF-335, BF-336, BF-337, BF-338, BF-339, BF-340, BF-341, BF-342, BF-343, BF-344, BF-345, BF-346, BF-347, BF-348, BF-349, BF-350, BF-351, BF-352, BF-353, BF-354, BF-355, BF-356, BF-357, BF-358, BF-359, BF-360, BF-361, BF-362, BF-363, BF-364, BF-365, BF-366, BF-367, BF-368, BF-369, BF-370, BF-371, BF-372, BF-373, BF-374, BF-375, BF-376, BF-377, BF-378, BF-379, BF-380, BF-381, BF-382, BF-383, BF-384, BF-385, BF-386, BF-387, BF-388, BF-389, BF-390, BF-391, BF-392, BF-393, BF-394, BF-395, BF-396, BF-397, BF-398, BF-399, BF-400, BF-401, BF-402, BF-403, BF-404, BF-405, BF-406, BF-407, BF-408, BF-409, BF-410, BF-411, BF-412, BF-413, BF-414, BF-415, BF-416, BF-417, BF-418, BF-419, BF-420, or BF-421.

7. The method according to claim 1, wherein step (a) comprises isoelectric focussing followed by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE).

8. A method for screening, diagnosis or prognosis of breast cancer in a subject, for determining the stage or severity of breast cancer in a subject, for identifying a subject at risk of developing breast cancer, or for monitoring the effect of therapy administered to a subject having breast cancer, said method comprising quantitatively detecting, in a sample of breast tissue from the subject, at least one of a Breast Cancer-Associated Protein Isoform (BPI) selected from the group consisting of: BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380.

9. The method according to claim 8, wherein the step of quantitatively detecting comprises testing at least one aliquot of the sample, said step of testing comprising:

- (a) contacting the aliquot with an antibody that is immunospecific for a preselected BPI; and
- (b) quantitatively measuring any binding that has occurred between the antibody and at least one species in the aliquot.

10. The method according to claim 9, wherein the antibody is a monoclonal antibody.

11. The method according to claim 9, wherein the step of quantitatively detecting comprises testing a plurality of aliquots with a plurality of antibodies for quantitative detection of a plurality of preselected BPIs.

12. The method according to claim 11, wherein the antibodies are monoclonal antibodies.

13. A preparation comprising an isolated Breast Cancer-Associated Protein Isoform (BPI) selected from the group comprising: BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380.

14. A kit comprising the preparation of claim 13.

15. An antibody capable of immunospecific binding to a Breast Cancer-Associated Protein Isoform (BPI) selected from the group consisting of: BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380.

16. The antibody of claim 15, which is a monoclonal antibody.

17. The antibody of claim 15, which binds to the BPI with greater affinity than to another isoform of the BPI.

18. The antibody of claim 15, which binds to the BPI with greater affinity than to any other isoform of the BPI.

19. A kit comprising the antibody of claim 15.

20. A pharmaceutical composition comprising a therapeutically effective amount of an antibody of claim 15 and a pharmaceutically acceptable carrier.

21. A pharmaceutical composition comprising:
a therapeutically effective amount of a fragment or derivative of an antibody of claim 15, said fragment or derivative containing the binding domain of the antibody; and
a pharmaceutically acceptable carrier.

22. A method of treating or preventing breast cancer comprising administering to a subject in need of such treatment or prevention a therapeutically effective amount of a nucleic acid encoding a Breast Cancer-Associated Protein Isoform (BPI) selected from the group consisting of: BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380.

23. A method of treating or preventing breast cancer comprising administering to a subject in need of such treatment or prevention a therapeutically effective amount of a nucleic acid that inhibits the function of one or more of a Breast Cancer-Associated Protein Isoform (BPI) selected from the group consisting of: BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380.

24. The method of claim 23, wherein the nucleic acid is a BPI antisense nucleic acid or ribozyme.

25. A method of screening for agents that interact with a BPI, a BPI fragment, or a BPI-related polypeptide, said method comprising:

(a) contacting a BPI, a biologically active portion of a BPI, or a BPI-related polypeptide with a candidate agent; and

(b) determining whether or not the candidate agent interacts with the BPI, the BPI fragment, or the BPI-related polypeptide.

26. The method of claim 25, wherein the BPI, the BPI fragment, or the BPI-related polypeptide is expressed by cells.

27. The method of claim 25, wherein the cells express a recombinant BPI, a recombinant BPI fragment, or a recombinant BPI-related polypeptide.

28. A method of screening for agents that modulate the expression or activity of a BPI or a BPI-related polypeptide comprising:

(a) contacting a first population of cells expressing a BPI or a BPI-related polypeptide with a candidate agent;

(b) contacting a second population of cells expressing said BPI or said BPI-related polypeptide with a control agent; and

(c) comparing the level of said BPI or said BPI-related polypeptide or mRNA encoding said BPI or said BPI-related polypeptide in the first and second populations of cells, or comparing the level of induction of a cellular second messenger in the first and second populations of cells.

29. The method of claim 28, wherein the level of said BPI or said BPI-related polypeptide, mRNA encoding said BPI or said BPI-related polypeptide, or said cellular second messenger is greater in the first population of cells than in the second population of cells.

30. The method of claim 28, wherein the level of said BPI or said BPI-related polypeptide, mRNA encoding said BPI or said BPI-related polypeptide, or said cellular second messenger is less in the first population of cells than in the second population of cells.

31. A method of screening for or identifying agents that modulate the expression or activity of a BPI or a BPI-related polypeptide comprising:

(a) administering a candidate agent to a first mammal or group of mammals;

(b) administering a control agent to a second mammal or group of mammals; and

(c) comparing the level of expression of the BPI or the BPI-related polypeptide or of mRNA encoding the BPI or the BPI-related polypeptide in the first and second groups, or comparing the level of induction of a cellular second messenger in the first and second groups.

32. The method of claim 31, wherein the mammals are animal models for breast cancer.

33. The method of claim 31, wherein the level of expression of said BPI or said BPI-related polypeptide, mRNA encoding said BPI or said BPI-related polypeptide, or of said cellular second messenger is greater in the first group than in the second group.

34. The method of claim 31, wherein the level of expression of said BPI or said BPI-related polypeptide, mRNA encoding said BPI or said BPI-related polypeptide, or of said cellular second messenger is less than in the first group than in the second group.

35. The method of claim 31, wherein the levels of said BPI or said BPI-related polypeptide, mRNA encoding said BPI or said BPI-related polypeptide, or of said cellular second messenger in the first and second groups are further compared to the level of said BPI or said BPI-related polypeptide or said mRNA encoding said BPI or said BPI-related polypeptide in normal control mammals.

36. The method of claim 31, wherein administration of said candidate agent modulates the level of said BPI or said BPI-related polypeptide, or said mRNA encoding said BPI or said BPI-related polypeptide, or said cellular second messenger in the first group towards the levels of said BPI or said BPI-related polypeptide or said mRNA or said cellular second messenger in the second group.

37. The method of claim 31, wherein said mammals are human subjects having breast cancer.

38. A method of screening for or identifying agents that interact with a BPI or a BPI-related polypeptide, comprising

- (a) contacting a candidate agent with the BPI or the BPI-related polypeptide, and
- (b) quantitatively detecting binding, if any, between the agent and the BPI or the BPI-related polypeptide.

39. A method of screening for or identifying agents that modulate the activity of a BPI or a BPI-related polypeptide, comprising

- (a) in a first aliquot, contacting a candidate agent with the BPI or the BPI-related polypeptide, and
- (b) comparing the activity of the BPI or the BPI-related polypeptide in the first aliquot after addition of the candidate agent with the activity of the BPI or the BPI-related polypeptide in a control aliquot, or with a previously determined reference range.

40. The method according to claim 38, wherein the BPI or the BPI-related polypeptide is recombinant protein.

41. The method according to claim 38, wherein the BPI or the BPI-related polypeptide is immobilized on a solid phase.

42. A method for screening, diagnosis or prognosis of breast cancer in a subject or for monitoring the effect of an anti-breast cancer drug or therapy administered to a subject, comprising:

- (a) contacting at least one oligonucleotide probe comprising 10 or more consecutive nucleotides complementary to a nucleotide sequence encoding a BPI selected from the group consisting of BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243,

BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380 with an RNA obtained from a biological sample from the subject or with cDNA copied from the RNA wherein said contacting occurs under conditions that permit hybridization of the probe to the nucleotide sequence if present;

(b) detecting hybridization, if any, between the probe and the nucleotide sequence; and

(c) comparing the hybridization, if any, detected in step (b) with the hybridization detected in a control sample, or with a previously determined reference range.

43. The method of claim 42, wherein step (a) comprises contacting a plurality of oligonucleotide probes comprising 10 or more consecutive nucleotides complementary to a nucleotide sequence encoding a BPI selected from the group consisting of BPI-1, BPI-2, BPI-3, BPI-4, BPI-5, BPI-6, BPI-7, BPI-8, BPI-11, BPI-12, BPI-20, BPI-21, BPI-23, BPI-24, BPI-25, BPI-28, BPI-30, BPI-31, BPI-33, BPI-34, BPI-35, BPI-36, BPI-37, BPI-38, BPI-39, BPI-40, BPI-42, BPI-47, BPI-57, BPI-58, BPI-64, BPI-65, BPI-68, BPI-69, BPI-70, BPI-71, BPI-72, BPI-201, BPI-202, BPI-203, BPI-204, BPI-205, BPI-206, BPI-207, BPI-208, BPI-209, BPI-210, BPI-211, BPI-212, BPI-213, BPI-214, BPI-215, BPI-216, BPI-217, BPI-218, BPI-219, BPI-220, BPI-221, BPI-222, BPI-223, BPI-224, BPI-225, BPI-226, BPI-227, BPI-228, BPI-229, BPI-231, BPI-232, BPI-233, BPI-234, BPI-235, BPI-236, BPI-237, BPI-238, BPI-239, BPI-240, BPI-241, BPI-242, BPI-243, BPI-244, BPI-245, BPI-246, BPI-247, BPI-248, BPI-249, BPI-250, BPI-251, BPI-252, BPI-253, BPI-254, BPI-255, BPI-256, BPI-257, BPI-258, BPI-259, BPI-260, BPI-261, BPI-262, BPI-263, BPI-264, BPI-265, BPI-266, BPI-

267, BPI-268, BPI-269, BPI-270, BPI-271, BPI-272, BPI-273, BPI-274, BPI-276, BPI-277, BPI-278, BPI-279, BPI-280, BPI-281, BPI-282, BPI-283, BPI-301, BPI-302, BPI-303, BPI-304, BPI-306, BPI-308, BPI-309, BPI-311, BPI-312, BPI-313, BPI-314, BPI-315, BPI-316, BPI-317, BPI-318, BPI-319, BPI-320, BPI-321, BPI-322, BPI-323, BPI-324, BPI-325, BPI-326, BPI-327, BPI-328, BPI-329, BPI-330, BPI-331, BPI-332, BPI-333, BPI-334, BPI-335, BPI-336, BPI-337, BPI-338, BPI-339, BPI-340, BPI-341, BPI-342, BPI-343, BPI-344, BPI-346, BPI-347, BPI-348, BPI-349, BPI-350, BPI-352, BPI-353, BPI-354, BPI-355, BPI-356, BPI-357, BPI-358, BPI-359, BPI-360, BPI-361, BPI-362, BPI-363, BPI-364, BPI-365, BPI-366, BPI-367, BPI-368, BPI-369, BPI-370, BPI-371, BPI-372, BPI-374, BPI-376, BPI-378, BPI-379, or BPI-380 with an RNA obtained from a biological sample from the subject or with cDNA copied from the RNA wherein said contacting occurs under conditions that permit hybridization of the probe to the nucleotide sequence if present.

44. The method of claim 42, wherein step (a) includes the step of hybridizing the nucleotide sequence to a DNA array, wherein one or more members of the array are the probes complementary to a plurality of nucleotide sequences encoding distinct BPIs.